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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,223	04/15/2004	Philip C. Hartstein	OPTIS.090A	7253

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EXAMINER	
WHITE, DENNIS MICHAEL	
ART UNIT	**PAPER NUMBER**
4151	

NOTIFICATION DATE	DELIVERY MODE
03/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/825,223	HARTSTEIN ET AL.	
	Examiner	Art Unit	
	DENNIS M. WHITE	4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/20/2004,12/03/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-11, 13-15, 17-18, 20, 22, 23-33 rejected under 35 U.S.C. 102(b) as being anticipated by Staehlin (US 5,636,640).

Regarding claim 1 and 23, Staehlin teaches an apparatus for sampling blood ("a sample element for holding a volume of bodily fluid drawn from the skin of a patient at a withdrawal site") comprising: a housing defining a sample chamber; and a pierceable membrane ("barrier") having a first side configured to contact the skin of the patient where the skin is punctured ("withdrawal site" "disposed across said flow path" "configured to contact the skin of a patient at a lancing site"), and a second side in fluid communication with said sample chamber, the barrier being configured to be pierced by a sharpened tip ("lance") (Figure 1:56), to allow liquid to be drawn through the opening into the chamber ("permit said bodily fluid to pass from said first side to said second side") (Abstract). Specifically regarding claim 23, Staehlin teaches the liquid passing from the patient to the sample chamber via a communicative passage ("a flow path extending from said sample chamber") (Figure 4a: from piercing site to 20). The passage has a first side being enclosed on all sides (Figure 4a:4) except

where the passage joins said sample chamber (Figure 4a: 62) such that, upon formation of an opening in the membrane, fluid may flow from the first side of the membrane, through the communicative passage ("flow path") and into the sample chamber (col. 3 lines 35-54)

Regarding claim 2, Staehlin teaches the pierceable membrane to be air impermeable ("formed from a substantially nonporous material") (col. 3 lines 25-27).

Regarding claim 3, Staehlin teaches the membrane ("barrier") before being punctured is air impermeable ("in the absence of an opening pierced therein, is configured to permit substantially none of said bodily fluid to pass from said first side to said second side") (col. 3 lines 25-27).

Regarding claim 4, Staehlin teaches the liquid to be drawn through the opening and into the chamber ("configured to permit substantially none of said bodily fluid to pass from said second side to said first side") when the piercer member punctures the pierceable membrane to form an opening and engage the object ("placed against the skin of a patient and pierced") (col. 2 lines 5-12).

Regarding claim 5, Staehlin teaches an adhesive ring ("adhesive") disposed on said first side of said barrier (Figure 7a:6, col. 5 lines 30-34).

Regarding claims 6 and 26, Staehlin teaches the sample chamber is reagentless (Figure 6a: 20).

Regarding claims 7 and 27, Staehlin teaches the sample chamber is at least partially defined by a window (col. 1 lines 55-60).

Regarding claims 8 and 28, Staehlin teaches the window is transmissive of infrared radiation (col. 1 lines 55-60 and col. 5 lines 16-21).

Regarding claims 9 and 29, Staehlin teaches the membrane ("barrier") is more easily pierced by a lance than is said window when the window is disposed above the reservoir (Figure 9: 20, col. 6 line 44-46).

Regarding claims 10 and 30, Staehlin teaches the membrane (Figure 6a:7) is more easily pierced by a lance (Figure 6a:56) than the adjacent portion of the housing (Figure 6a:43).

Regarding claims 11 and 31, Staehlin teaches a communicative ("supply") passage (Figure 2:17) extending from the sample chamber (Figure 2:20), the supply passage having a first sidewall (Figure 4b: sidewall of 17 not numbered but shown) adjacent to the membrane ("barrier"), the membrane is more easily pierced by a lance than is said first sidewall (Figure 4a).

Regarding claim 24, Staehlin teaches the membrane side ("second side") within a chamber (Figure 4a:4) is in fluid communication with the sample chamber (Figure 4a:20).

Regarding claim 25, Staehlin teaches the membrane is pierceable (Abstract) to permit bodily fluid to pass through the membrane.

Regarding claim 32, Staehlin teaches the liquid flow path comprises a communicative passage ("a supply passage") (Figure 5: 17, col. 5 lines 1-5).

Regarding claim 33, Staehlin teaches the liquid flow path comprises a communicative passage ("a supply passage") (Figure 5: 17, col. 5 lines 1-5) and a passageway ("entry chamber") (Figure 2:62) is oriented to be in line ("in fluid

communication") with a communicative passage ("supply passage") (col. 3 lines 50-53).

Regarding claim 13, Staehlin teaches a method of drawing a blood ("bodily fluid") from the epidermis ("skin") of a patient at a piercing ("withdrawal") site (col. 1 line 27-42). The method comprising: placing a first side of a pierceable membrane ("barrier") against the epidermis ("skin of the patient") at the piercing site ("said withdrawal site"); piercing the membrane and puncturing the epidermis ("forming a first opening through said barrier and a second opening in the skin of the patient at said withdrawal site"), the membrane and epidermis openings are ("said first opening and said second opening") allow for blood to pass to the sample chamber ("being in fluid communication; and placing a sample chamber in fluid communication with a second side of said barrier") (Figure 3: 7 to 20).

Regarding claim 14, Staehlin teaches the method wherein the sample chamber is in fluid communication with outside surface of the membrane after the membrane is pierced ("placing said sample chamber in fluid communication with said second side of said barrier, comprises placing said sample chamber in fluid communication with said first opening") (col. 2 line 1-13).

Regarding claim 15, Staehlin teaches causing the liquid to ("bodily fluid") empty into ("flow into") the sample reservoir or chamber (col. 3 lines 55-65, Figure 5:20).

Regarding claim 17, Staehlin teaches the method further comprising affixing said first side of said barrier to the skin of the patient with an adhesive or sealing ring (col. 4 lines 60-67).

Regarding claim 18, Staehlin inherently teaches the removing of the membrane ("said barrier") from the skin of the patient after the piercer retracts to its original position because the apparatus would not remain attached to the patient (col.1 lines 26-42).

Regarding claim 20, Staehlin teaches the method comprising monitoring changes in infrared transmissibility ("analyzing the liquid") (col. 5 lines 16-19).

Regarding claim 22, Staehlin teaches the method of providing sampling and testing liquid in a single step with a totally evacuated sealed sterile assembly ("reducing, with said barrier, the degree to which contaminants from the surface of the skin of the patient enter said bodily fluid") (col. 1 lines 17-20).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 12, 16, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staehlin in view of Wong et al (US 6,312,888).

Staehlin teaches the limitations of claims 1, 13, 15, and 23 as per above.

Regarding claims 12 and 34, Staehlin is silent about the sample element further comprising a separator located between said second side of said barrier and said sample chamber and located in said flow path. Wong et al teaches an article for monitoring the concentration of an analyte in blood. The article further

comprises a sample introduction chamber that contains a blood separation filter to filter out red blood cells (Wong: col. 11 lines 55-65). It would have been obvious to one of ordinary skill in the art as motivated by Wong et al to cause the blood in the apparatus of Staehlin to flow through a separator because it allows some applications to be performed in which no red blood cells are desired because they might interfere with the measurements (col. 11 lines 55-65).

Regarding claim 16, Staehlin is silent about causing the bodily fluid to flow through a separator before flowing into the sample chamber. Wong et al teaches a method for monitoring the concentration of an analyte in blood. The method further comprises causing the blood to pass through a blood separation filter to filter out red blood cells. It would have been obvious to one of ordinary skill in the art as motivated by Wong et al to cause the blood in the method of Staehlin to flow through a separator because it allows some applications to be performed in which no red blood cells are desired because they might interfere with the measurements (col. 11 lines 55-65).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staehlin in view of Simons et al (US 5,871,494).

Staehlin teaches the limitations of claims 13 and 18 as per above.

Regarding claim 19, Staehlin is silent about removing residual bodily fluid from the piercing ("withdrawal") with the membrane. Simons et al teach a method of blood analysis using an apparatus for obtaining blood for analysis from the skin of a patient with a controlled degree of lancing. The method further comprises using an absorbent material for absorbing residual blood from the

wound after lancing and testing (Simons: col. 6 lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of removing the residual bodily fluid of Simons et al in the method of Staehlin because it avoids contact with bodily fluids after the analysis.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staehlin in view of Levaughn et al (US 6,283,982).

Staehlin teaches the limitations of claim 13 as per above.

Regarding claim 21, Staehlin is silent about the method further comprising minimizing after-bleed. Levaughn et al teach a method for self-collecting a sample of body fluid by penetrating a body tissue at a sampling site. The method further comprises minimizing the size of the wound to reduce the incident of residual bleeding ("minimizing after-bleed") (col. 3 lines 1-8). It would have been obvious to one of ordinary skill in the art as motivated by Levaughn et al to provide a method of minimizing after-bleeding because it avoids staining the user's clothing (col. 3 lines 1-8).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Garcia et al (US 4,787,398) and Bojan et al (US 2002/099308) are X references cited in the International Search report but were not relied upon because Staehlin anticipates the base claims of this invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number

is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Kornakov can be reached on 571-272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dmw

/Michael Kornakov/
Supervisory Patent Examiner, Art Unit 4151